7-31-95

Chemical Code: 113201 Date out: 31 JUL 1995

31 JUL 1995

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Bruce Sidwell/Mark Wilhite
Special Review and Reregistration Division (7508W) and

[redacted]
Registration Division (7505C)

From: Paul J. Mastradone, Ph.D., Chief, Review Section 1
Environmental Fate & Ground Water Branch/EFED (7507C)

Thru: Henry M. Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (7507C)

Attached, please find the EFGWB review of...

DP Barcode:	D165556, 172180, 172184, 172187, 180454, 180848, 182128, 183906, 189301, 190221, 193639, 197668, 200149, 204484, 211115, 211724		
Common Name:	Vinclozolin	Trade name:	Ronilan
Company Name:	BASF		
ID #:	113201		
Purpose:	Prepare EFGWB RED Chapter, review new uses		

Type Product:	Action Code:	EFGWB #(s):	Review Time:
Fungicide		N/A	50

STATUS OF STUDIES IN THIS PACKAGE: STATUS OF DATA REQUIREMENTS:

Guideline #	MRID	Status[1]	Status[2]
161-1	41471006	U	P
161-2	42394706	S	S
161-3	41471008	U	N
162-1	43013001	U	N
162-2	41471009	A	S
162-3	43013002	C	N
163-1	41471010, 41888904, 41496904	U	N
163-2	42513101	A	S
164-1	41538301, 42687601, 42717401, 43102601, 42327301	U	N
165-4	42847001	A	S

[1]Study Status Codes: A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
[2]Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Chemical: Vinclozolin
Case No: 2740
Chemical No: 113201
Barcode Nos: D165556, 172180, 172184, 172187, 180454, 180848, 182128, 183906, 189301, 190221, 193639, 197666, 200149, 204484, 211115, 211724

MEMORANDUM

SUBJECT: Vinclozolin - List B RED Candidate

FROM: Henry M. Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (7507C)

Henry Jacoby 8/1/95

TO: Jay Ellenberger, Chief
Accelerated Reregistration Branch
Special Review and Reregistration Branch (7508W)

AND: Evert Byington, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (7507C)

Attached is the Environmental Fate and Ground Water Branch package for the vinclozolin List B RED. The package contains the EFGWB RED chapter, a 12-pointer which includes an environmental fate assessment and separate ground water and surface water assessments, and science reviews of environmental fate studies received by EFGWB.

The LUIS report indicates that there are forestry uses for vinclozolin. Because the forestry use could result in exposure to aquatic systems from foliar application to broadleaf trees and conifers, aerobic aquatic metabolism data (162-3) should be submitted. Also, forest field dissipation data (164-3) are needed to assess the fate of vinclozolin under typical forest use conditions. Neither of these studies has been submitted. In addition, the information needed to fulfill the unsatisfied data requirements supporting the terrestrial uses of vinclozolin are needed to support the forestry use (see below).

Although several environmental fate data requirements are unfulfilled at this time (hydrolysis [161-1], photodegradation on soil [161-3], aerobic soil metabolism [162-1], leaching and adsorption/desorption [163-1], and terrestrial field dissipation [164-1]), there is sufficient information to allow a qualitative environmental fate assessment for vinclozolin. The specific information needed to fulfill each data requirement is outlined in section 7.2

of the attached 12-pointer. Also, spray drift data (Droplet size spectrum [201-1] and Drift field evaluation [201-1]) may be requested by EFED/EFGWB if EFED/EEB and/or HED need data to assess exposure to nontarget organisms to support aerial, air-blast, or ground application methods.

Generally, submission of the requested information will enhance EFGWB's confidence in the data, but is not likely to affect substantially the environmental fate assessment for vinclozolin. In two cases, however, EFGWB believes that the requested data are particularly important. First, K_d values have been requested for metabolite B. These will enable a more quantitative estimate of the potential mobility of this key degradation product which is formed early in the degradation process in relatively large concentrations. Given its rapid formation, it is possible that metabolite B has biological activity and contributes to the pesticidal properties of vinclozolin. Soil column studies indicate that metabolite B is potentially mobile, but the information available from these studies is only qualitative. K_d's for metabolite B may be needed for model simulations which assess the potential of vinclozolin residues to contaminate surface waters. Also, frozen storage stability data for individual analytes (parent vinclozolin plus metabolites B, D, and E) in soil are needed to increase confidence in the field dissipation studies. This information is important because much of EFGWB's assessment is based on four field dissipation studies.

Environmental Fate Assessment

Acceptable and supplemental laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis (soil metabolism), abiotic degradation, and transport with water. N-(3,5-dichlorophenyl) carbamic acid (1-carboxyl-1-methyl)-2-propenyl ester (metabolite B or BF 352-22) is a common degradate of hydrolysis, soil metabolism, and photolysis. Because metabolite B is formed rapidly and in relatively large concentrations at environmental pH, it may have biological activity and contribute to the pesticidal properties of parent vinclozolin. The other principal degradation products of vinclozolin are 3,5-dichloroaniline (metabolite D or BF 352-31), and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (metabolite E or BF 352-23). Other degradates are formed in smaller concentrations. Metabolite E, which appears to be a degradation product of parent and metabolite B, degrades to 3,5-dichloroaniline (metabolite D) which appears to resist further degradation. Metabolites B, D, and E are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter.

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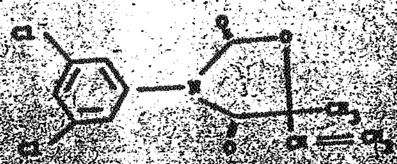
1.0 CHEMICAL:

Common Name: Vinclozolin

Chemical Name: 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione

Chemical Structure:



Chemical/physical properties:

Molecular Weight:	286.11
Empirical Formula:	$C_{12}H_9NO_3Cl_2$
Melting Point:	106-108°C (from *Farm Chemicals Handbook*)
Solubility (H_2O):	2.6 mg/L @20°C
Vapor Pressure:	3.4×10^{-6} mbar at 25°C (2.6×10^{-6} mm Hg)
K_{ow}	1054

2.0 TEST MATERIAL: See individual DERs.

3.0 STUDY/ACTION TYPE:

Review environmental fate data, prepare an environmental fate assessment, and review new uses for the EFED RED Chapter.

4.0 STUDY IDENTIFICATION: See attached DERs.

5.0 REVIEW SCIENTIST:

Arnet W. Jones, Agronomist
Review Section 1
OPP/EFED/EFGWB

Signature: Arnet W. Jones

Date: 31 JUL 1995

6.0 APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Review Section 1
OPP/EFED/EFGWB

Signature: Paul J Mastradone

Date: 31 JUL 1995

7.0 CONCLUSIONS:

7.1 Although several environmental fate data requirements are unfulfilled at this time (hydrolysis [161-1], photodegradation on soil [161-3], aerobic soil metabolism [162-1], leaching and adsorption/desorption [163-1], and terrestrial field dissipation [164-1]), there is sufficient information to allow a qualitative environmental fate assessment for vinclozolin. Also, to support vinclozolin's forestry uses, aerobic aquatic metabolism (162-4) and forest field dissipation (164-3) data are needed. See Recommendations.

Acceptable and supplemental laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis (soil metabolism), abiotic degradation, and transport with water. N-(3,5-dichlorophenyl) carbamic acid (1-carboxyl-1-methyl)-2-propenyl ester (metabolite B or BF 352-22) is a common degradate of hydrolysis, soil metabolism, and photolysis. Because metabolite B is formed rapidly and in relatively large concentrations at environmental pH, it may have biological activity and contribute to the pesticidal properties of parent vinclozolin. The other principal degradation products of vinclozolin are 3,5-dichloroaniline (metabolite D or BF 352-31) and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (metabolite E or BF 352-23). Other degradates are formed in smaller concentrations. Metabolite E, which appears to be a degradation product of parent and metabolite B, degrades to 3,5-dichloroaniline (metabolite D) which appears to resist further degradation. Metabolites B, D, and E are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter.

7.2 The following environmental fate studies were submitted and have been reviewed. See DERs for details.

(a) Hydrolysis (161-1)

The data requirement is partially fulfilled by a study which provides data on the hydrolysis of vinclozolin at pH 7 and 9 (MRID 41471006). Hydrolysis data for pH 5 are supplemental. Hydrolysis appears to be a route of vinclozolin dissipation in the environment; alkaline hydrolysis is very rapid.

Sterile aqueous buffered solutions of vinclozolin incubated in darkness at 25 ± 1°C at 7 and 9 hydrolyzed with respective half-lives of 31.3 hr and 37.9 min. At pH 7, two major degradates, N-(3,5-dichlorophenyl)carbamic acid (1-carboxy-1-methyl)-2-propenyl ester (BF 352-22 or metabolite B) and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (BF 352-23 or metabolite E), were identified and reached their respective maximum reported concentrations of 76.4% and 16.8% of the applied radioactivity at day 5 (120 h). At pH 9, metabolites B and E reached their maximum reported concentrations at 120 min when they contained 68.7% and 20.9% of the applied, respectively.

At pH 5, vinclozolin and metabolite B appeared to reach chemical steady-state in approximately 5 days. The ratio of vinclozolin to metabolite B remained relatively constant (1:0.8) from days 10 to 36. At pH 5 a half-life of 41.8 days was calculated for parent; for combined residues of parent and metabolite B a half-life of 89.4 days was reported. At pH 5 metabolite E was found at its maximum concentration (25.6% of the applied radioactivity) at day 34. To fulfill the data requirement additional information is needed for hydrolysis of vinclozolin at pH 5. The study indicates that at pH 5 vinclozolin and metabolite B reached equilibrium although evidence to support this was not presented. Because hydrolysis is an important degradation process for vinclozolin, additional evidence (e.g. a proposed mechanism for re-formation of parent and the kinetics for the reaction) is needed to support the study's results for pH 5. See Study 1 for details.

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(b) Photodegradation in water (161-2)

One study was submitted which provides acceptable information on the photodegradation of vinclozolin in water (MRID 42394706). Photodegradation in water appears to be a route of vinclozolin dissipation in the environment. The data requirement is fulfilled; no additional photodegradation in water data are needed for vinclozolin at this time.

In a 31-day study, ring-labeled vinclozolin in pH 5 buffered solution was incubated at 25 ± 1°C and exposed to simulated sunlight in 12 hr light/12 hr dark periods. In the irradiated group, the half-life of vinclozolin was 15.9 days; in dark controls the half-life was 38.1 days. The corrected photodegradation half-life for 12 hr light/12 hr dark period (i.e., eliminating hydrolysis effects) was reported as 27.2 days. In addition to parent, metabolites B and E were the major compounds identified. The largest reported concentrations of metabolites B (26.6% of the total recovered radioactivity) and E (10.5% of TRR) occurred on days 9 and 16, respectively. The principal degradates detected in dark controls were metabolite B (maximum reported concentration of 36.9% of TRR at day 9) and metabolite E (maximum reported concentration of 24.3% of TRR at day 31).

(c) Photodegradation on soil (161-3)

One study which provides supplemental information regarding the photodegradation of vinclozolin on soil was submitted (MRID 41471008). Vinclozolin appears to photodegrade on soil.

In a 30-day study, uniformly ^{14}C ring-labeled vinclozolin applied to a sandy loam soil at a nominal rate of 10 ppm and irradiated with simulated sunlight on a 12 hr light/12 hr dark cycle degraded with a half-life of 18.1 days. Three degradates - metabolite B, metabolite E, and N-(3,5-dichlorophenyl)-5-methyl-2,4-oxazolidinedione (metabolite S or BF 352-41) - were detected in irradiated samples in maximum concentrations of 12.9% (day 3), 5.4% (day 3), and 32.7% (day 1) of the initially applied radioactivity, respectively. $^{14}CO_2$ and soil-bound residues accounted for 14.4% and 19.5% of the applied radioactivity at day 30, respectively. In dark controls, where the half-life was 37.2 days, metabolite B was found at a maximum concentration of 15.2% of the applied at day 30 and metabolite S was at its maximum concentration (38.2%) at day 8. Neither metabolite E nor $^{14}CO_2$ was detected in dark controls.

To upgrade the study to acceptable and fulfill the data requirement, the registrant should: (a) explain the presence of large quantities of metabolite S at time zero and later in the study, particularly in dark controls; and (b) provide data which demonstrate that the artificial light source used compares favorably with natural sunlight. See Study 3 for details.

(d) Aerobic soil metabolism (162-1)

One supplemental study was submitted which does not fulfill the data requirement because an exaggerated application rate appeared to affect the kinetics of vinclozolin degradation (MRID 43013001). Earlier aerobic soil metabolism studies were judged supplemental because storage stability of vinclozolin and its degradates in frozen soil were not available (MRIDs 88288, 136376, 136377; see EFGWB's Phase 4 review of 03/25/91). The data requirement remains unfulfilled at this time because storage stability data have not been submitted. See studies 4 and 16 for details.

In a 371-day study, phenyl-labeled vinclozolin applied to a loamy sand soil at 63.9 ppm (10 times the maximum labeled rate) and incubated aerobically at 25 ± 0.5°C degraded with a half-life of 352 days. Metabolite B was detected by TLC in quantities of up to 2.3% of total radioactive residues (TRR) at all sampling intervals between 15 and 371 days after treatment (DAT). Metabolite D (3,5-dichloroaniline) was detected in concentrations of 0.3 to 1.1% of TRR at all sampling intervals between 133 and 371 DAT. Metabolite E was detected by TLC in concentrations of 1.1%, 1.0%, and 0.5% of TRR at 133, 185, and 251 DAT, respectively. By the end of the study, 1.5% of TRR was bound to soil and <1% of TRR was trapped as volatile compounds. Virtually all volatile residues were identified as $^{14}CO_2$.

(e) Anaerobic soil metabolism (162-2)

One acceptable study which fulfills the data requirement was submitted (MRID 41471009). Vinclozolin is metabolized in soil under anaerobic conditions. No additional anaerobic soil metabolism data are needed at this time.

In a 76-day study, uniform ring-labeled vinclozolin was applied to moist loamy sand soil. Soil was incubated in darkness at 22 ± 2°C aerobically for 14 days followed by a 62-day anaerobic incubation period. Vinclozolin residues declined from 6.61 ppm at day 0 to 2.44 ppm at day 14 (the end of the aerobic incubation period). During the anaerobic phase (days 14-76) when residues declined from 2.44 to 0.21 ppm, the reviewer-calculated half-life was 17.6 days. The reported half-life for parent vinclozolin (aerobic + anaerobic conditions) was 15.33 days. Metabolites B, E, and D were detected in maximum concentrations of 35.7%, 3.5%, and 3.8% of the applied radioactivity, respectively. By day 76, soil-bound residues and volatile compounds accounted for approximately 48% and 0.4% of the applied radioactivity, respectively.

(f) Anaerobic aquatic metabolism (162-4)

One supplemental study was reviewed which does not fulfill the data requirement because the exaggerated application rate used appeared to affect the rate of vinclozolin degradation (MRID 43013002). However, a separate acceptable study fulfills the anaerobic soil metabolism data requirement (162-2) for vinclozolin (see Study 5). According to SRRD there are no current aquatic uses of vinclozolin which would require the submission of another anaerobic aquatic metabolism study. Therefore, no additional anaerobic aquatic metabolism data for vinclozolin are needed at this time.

In a 371-day study, phenyl-labeled vinclozolin added to a flooded loamy sand soil at a rate of 62.7 ppm degraded with a half-life of 134 days. The half-life of vinclozolin in sediment only was 87.4 days. Total vinclozolin residues (soil phase plus water phase) declined from 74.8% of total recovered radioactivity (TRR) at day zero to 8.0% TRR at 371 days after treatment (DAT). The principal degradation products recovered were: metabolite B which contained 7% of TRR at day zero, increased to 57% of TRR at 64 DAT, and was 35% of TRR by 371 DAT; 3,5-dichloroaniline (metabolite D) which contained 0.7% of TRR at day zero and increased to 10.5% of TRR by 371 DAT; and metabolite E which remained relatively constant at 4-7% of TRR during the study.

(g) Leaching and adsorption/desorption (163-1)

Supplemental batch equilibrium studies for parent vinclozolin (MRID 41471010) and metabolites D and E (MRID 41888904) were submitted. The data indicate that vinclozolin and its principal degradates are potentially very mobile to slightly mobile in soil. The data in both studies are inconclusive because the K_{de} values reported are uniformly low and inconsistent with corresponding K_ds. Supplemental column leaching studies (MRIDs 136881, 41496904) also were submitted which indicate that parent and degradates are potentially mobile. To fulfill the data requirement, the registrant should explain the inconsistencies between K_d and corresponding K_{de} values in the batch equilibrium studies for parent and metabolites D and E. Also, because metabolite B is an important degradate, K_d values for metabolite B should be submitted for four soils. K_ds for metabolite B will enable a more precise assessment of the degradate's potential mobility and may also be needed for modeling.

In batch equilibrium studies parent vinclozolin was potentially very mobile to relatively mobile with reported Freundlich K_d values of 0.46, 3.82, 3.4, and 5.27 in sand, sandy loam, loam, and clay loam soils, respectively. The reported K_{des} values were 0.70-0.76 for all four soils. K_d was correlated with percent clay (r = 0.95), percent sand (r = -0.86), cation exchange capacity (r = 0.99), and soil organic matter content (r = 0.90). In similar studies metabolite D was potentially very mobile to relatively immobile with reported Freundlich K_d values of 0.58, 1.86, 2.60, and 10.01 for sand, sandy loam, loam, and clay loam soils, respectively. The respective reported K_{des} values were 0.11, 0.51, 0.41, and 0.08. Metabolite E was potentially very mobile to slightly mobile in the same soils with reported Freundlich K_d values of 0.65, 1.24, 1.66, and 6.73. The respective K_{des} values reported were 0.22, 0.94, 0.62, and 0.16. K_d for both metabolites increased with increasing soil organic matter, clay content, and cation exchange capacity.

Vinclozolin aged in soil for 30 days was added to columns of loamy sand and sandy loam soils of European origin and leached daily with 12.5 mm of water for 45 days. During the study 3.2% and 9.9% of the applied radioactivity was recovered in the leachate from the loamy sand (4.4% organic matter) and sandy loam (1.7% organic matter) soils, respectively. During the first 7 days, parent was the principal compound detected in leachate by TLC. Metabolite B was the primary compound detected by TLC after the first week of the 45-day study. The study indicates that metabolite B is mobile to relatively mobile in soil.

Uniformly phenyl-labeled vinclozolin residues aged aerobically for 40 days in darkness at 20 ± 2°C were very mobile in a column (50 mm inner diameter) of loamy sand soil after leaching the column with 1.3 L of water over a 2-day period. After leaching 34.2% of the recovered radioactivity was detect-

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ed in leachate, 47.8% was removed from soil, and 18% was soil-bound. Virtually all of the radioactivity detected in the leachate (82% of the recovered radioactivity) was present in metabolite B; no other compounds were identified in the leachate. Metabolite B was also the principal compound identified in the soil column. Metabolites D and E were less mobile than metabolite B and were detected in small quantities in various segments of the soil column. Parent vinclozolin degraded substantially during the study; only about 2.2% of the recovered radioactivity was detected in parent in various soil segments.

(h) Laboratory volatility (163-2)

One acceptable study was submitted (MRID 42513101) which fulfills the data requirement. No additional laboratory volatility data are needed at this time. Volatilization is not likely to be a significant route of vinclozolin dissipation in the environment.

In a 30-day study, volatilization of ^{14}C-vinclozolin from a sand soil was measured at 25 ± 2°C at two soil moisture levels (50% and 75% of field moisture capacity) and two air flow rates (100 and 200 mL/min). Volatile ^{14}C-residues did not exceed 7.1% of the initial measured dose of radioactivity. Most volatilized radioactivity was detected as vinclozolin; small amounts of ^{14}C were detected in metabolite B, metabolite E, and in unidentified compounds. Volatilization increased with soil moisture and air flow. Vapor pressures were 9.23×10^{-7} to 1.39×10^{-5} mm Hg depending upon sampling time, air flow rate, and soil moisture content. Less than 1% of the initial radioactivity was recovered as $^{14}CO_2$ for all treatments.

(i) Terrestrial field dissipation (164-1)

Four studies on multiple crops and locations were submitted (MRIDs 41538301, 42687601, 42717401, 43505907). The field data appear to be consistent with laboratory studies and indicate that vinclozolin dissipates by degradation and to some extent by transport with water. The 3,5-dichloroaniline moiety of the parent molecule appears to resist degradation and is somewhat mobile. Residues originating from parent vinclozolin may accumulate from year to year and be available for rotational crop uptake. Data on individual analytes (vinclozolin and metabolites B, D, E, and S) and for total residues (free and bound residues of vinclozolin and degradates which contain the 3,5-dichloroaniline moiety) were submitted. Frozen storage stability data are needed to support data on individual analytes and to fulfill the data requirement. In the absence of storage stability data for individual compounds, it may be necessary to substitute the total residue half-life for the individual analyte of interest in exposure assessments and modeling. See studies 12 through 16 for details.

In terrestrial field dissipation studies conducted in Florida, New York, Missouri, and California vinclozolin dissipated with linear half-lives of 34 to 94 days. Linear half-lives at other locations were longer, but EFGWB has limited confidence in them due to poor fit to a linear model and/or because very few data points were used in the calculations. Nonlinear DT_{50} (the time needed for 50% dissipation of residues) values for vinclozolin were <1 to 4 days in NY and MO studies. In these studies early rapid degradation of parent

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was followed by degradation at a slower rate, a phenomenon observed in two aerobic soil metabolism studies. Metabolites B and E were detected regularly in relatively low concentrations in the upper soil layer at most sites. Metabolite S also was detected intermittently. Metabolite D (3,5-dichloroaniline) was detected regularly and was the most persistent and mobile vinclozolin degradation product.

Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1000 days. Nonlinear DT_{50}s for total residues were 30 to 300 days. DT_{90}s of >2500 days for total residues were reported for bare ground and turf studies in MO and NY. Persistence for total residues appeared to be attributable to two factors: (1) dichloroaniline, which appears to be the terminal degradate and is the common moiety upon which total residues were determined, is relatively resistant to chemical and microbial mediated degradation, and (2) the method for total residues includes a base extraction which removed soil-bound residues. Bound residues were apparently not removed by the extraction procedure for individual compounds. Some movement of residues through the soil profile was noted with intermittent detections at 12-18, 18-24, and 24-30 inches. Metabolite D was the only individual analyte detected regularly deeper than 6 inches.

Study 16 (MRIDs 42327301, 40297404, 43255802) discusses frozen storage stability for soil samples analyzed by BASF Method 25, the common-moiety method which analyzes for all compounds containing the 3,5-dichloroaniline moiety. After 7 to 26 months in frozen storage at <-5°C, recoveries from soil fortified with vinclozolin were 80 to 107%. Recoveries for metabolites B, and E were 90-101%, 92-123%, respectively. Recoveries from soil fortified with metabolite D (3,5-dichloroaniline) were 72%, 86%, 58%, and 63% after 7, 13, 19, and 26 months, respectively. Because the method analyzes only for a derivative of 3,5-dichloroaniline, a moiety common to parent vinclozolin and all principal degradates, the study does not establish the frozen storage stability of the individual compounds (vinclozolin and metabolites B, D, and E) in soil. Frozen storage stability data for individual analytes are needed to support the fate studies.

(j) <u>Bioaccumulation in fish (165-4)</u>

An acceptable study fulfills the portion of the data requirement pertaining to uptake and depuration of vinclozolin by bluegill sunfish (MRID 136387, see Phase 4 Review). The study reviewed in this package (MRID 42847001) identified the nature of residues which accumulated in bluegill sunfish. Together the two studies fulfill the data requirement.

Following 14 days of exposure to vinclozolin at a nominal concentration of 0.45 mg/L, bluegill sunfish exhibited bioconcentration factors of 143X, 421X, and 279X for edible, non-edible, and whole fish tissue, respectively. Of residues in edible tissue, 2.7% of total radioactive residues (TRR) was parent vinclozolin, 0.2% was metabolite S, and 1.2% of TRR was metabolite D. In non-edible tissue, 29.7% of TRR was parent and 2.8% of TRR was present in metabolite S. Metabolite D was not detected in non-edible tissue. Unidentified spots comprised 2.8% and 11.0% of TRR in edible and non-edible tissue, respectively.

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7.3 Environmental Fate: Ground Water and Surface Water Assessment

Acceptable and supplemental laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis (soil metabolism), abiotic degradation, and transport with water. N-(3,5-dichlorophenyl) carbamic acid (1-carboxyl-1-methyl)-2-propenyl ester (metabolite B or BF 352-22) is a common degradate of hydrolysis, soil metabolism, and photolysis. Because metabolite B is formed rapidly and in relatively large concentrations at environmental pH, it may have biological activity and contribute to the pesticidal properties of parent vinclozolin. The other principal degradation products of vinclozolin are 3,5-dichloroaniline (metabolite D or BF 352-31) and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (metabolite E or BF 352-23). Other degradates are formed in smaller concentrations. Metabolite E, which appears to be a degradation product of parent and metabolite B, degrades to 3,5-dichloroaniline (metabolite D) which appears to resist further degradation. Metabolites B, D, and E are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter. Vinclozolin is not addressed in the *Pesticides in Ground Water Database*. Vinclozolin is applied to foliage, but data on the fate of the fungicide on plant leaves were not available. An understanding of the routes of dissipation from foliage would improve EFGWB's understanding of the fate of vinclozolin in the environment.

Vinclozolin degrades abiotically; metabolites B and E are the principal degradates. At pH 7 and 9 vinclozolin hydrolyzed with respective half-lives of 31.3 hr and 37.9 min. At pH 5, where vinclozolin and metabolite B appeared to reach a chemical steady state in about 5 days, the half-life of parent was 41.8 days. A half-life of 89 days was reported for the combined residues of vinclozolin and metabolite B. Vinclozolin photodegraded in sterile aqueous buffer solution at pH 6 and on soil with half-lives of 15.9 and 18.1 days, respectively. Half-lives in dark controls were 38.1 and 37.2 days, respectively. In the soil photolysis study, the degradate N-(3,5-dichlorophenyl)-5-methyl-2,4-oxazolidinedione (metabolite S or BF 352-41) was a major compound identified in irradiated and dark control samples. $^{14}CO_2$ was a degradate in irradiated soil indicating that mineralization may be light-catalyzed.

Microbial-mediated degradation plays an important role in vinclozolin's fate in the environment. Metabolites B, D, E, and S are the principal degradation products. In four supplemental aerobic soil metabolism studies, vinclozolin degraded with half-lives of 35-68 days. In two other experiments conducted in a German soil, early initial rapid degradation ($t\frac{1}{2}$ = 5-7 days) was followed by slower degradation ($t\frac{1}{2}$ = 46-50 days). In an exaggerated rate (63.9 ppm) study vinclozolin's half-life was 352 days. Less than 1% of the applied radioactivity was trapped as $^{14}CO_2$ in these studies. Following a 14-day aerobic soil incubation, vinclozolin incubated anaerobically for 62 days in degraded with a half-life of 15.3 days (aerobic + anaerobic conditions). Combined residues of parent and metabolite B degraded with a half-life of 59 days. Vinclozolin added to a flooded loamy sand soil at an exaggerated application rate (62.7 ppm) degraded with a half-life of 134 days.

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Vinclozolin residues are potentially very mobile to relatively immobile. In supplemental batch equilibrium studies parent vinclozolin was potentially very mobile to relatively mobile with reported Freundlich K_d values of 0.46, 3.82, 3.4, and 5.27 in sand, sandy loam, loam, and clay loam soils, respectively. Metabolite D was very mobile to relatively immobile with reported Freundlich K_d values of 0.58, 1.86, 2.60, and 10.01 for sand, sandy loam, loam, and clay loam soils, respectively. In the same soils metabolite E was very mobile to slightly mobile with respective Freundlich K_ds of 0.65, 1.24, 1.66, and 6.73. Adsorption was positively related to soil organic matter, clay content, and cation exchange capacity and inversely related to sand content. Aged vinclozolin residues were relatively mobile in soil column studies. Residues are likely to be more mobile in sandy soils low in organic matter. Volatilization of ^{14}C vinclozolin from a sand soil was relatively low and did not exceed 7.1% of the dosed radioactivity over 30 days.

Field data tend to confirm laboratory studies. In terrestrial field dissipation studies conducted in Florida, New York, Missouri, and California vinclozolin dissipated with linear half-lives of 34 to 94 days. Nonlinear DT_{50}s (the time needed for 50% dissipation of residues) were <1 to 4 days in NY and MO studies. In NY and MO early rapid degradation of parent was followed by slower degradation, a phenomenon observed in two aerobic soil metabolism studies. Metabolites B and E were detected regularly in relatively low concentrations in the upper soil layer at most sites. Metabolite S also was detected intermittently. Metabolite D (3,5-dichloroaniline) was detected regularly and was the most persistent and mobile vinclozolin degradation product. Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1000 days. Nonlinear DT_{50}s for total residues were 30 to 300 days. DT_{90}s of >2500 days for total residues were reported for bare ground and turf studies in MO and NY. Persistence of total residues appeared to be related to the resistance of metabolite D (dichloroaniline) to degradation and to the inclusion of bound residues in total residue data. Transport of residues with water was noted with intermittent residue detections at 12-18, 18-24, and 24-30 inches. Metabolite D was the only individual analyte detected regularly deeper than 6 inches.

Vinclozolin residues showed little potential to bioaccumulate in bluegill sunfish. Bioconcentration factors of 106-143X, 317-421X, and 241-279X were reported for edible, non-edible, and whole fish tissue, respectively. More than 97% of the accumulated residues depurated when exposed fish were placed in residue-free water.

Detailed ground water and surface water assessments are attached as separate documents. Also, see Recommendations.

7.4 New Uses

The LUIS report indicates that there are forestry uses for vinclozolin. Because the forestry use could result in exposure to aquatic systems from foliar application to broadleaf trees and conifers, aerobic aquatic metabolism data (162-3) should be submitted. Also, forest field dissipation data (164-3) are needed to assess the fate of vinclozolin under typical forest use conditions. In addition, the information needed to fulfill the unsatisfied data requirements supporting the terrestrial uses of vinclozolin are needed to support the forestry use.

Vinclozolin has been proposed for use on potatoes, succulent beans, and grapes. Vinclozolin could be applied to potatoes twice at a maximum rate of 2 lb a.i./A per application for a maximum of 4 lb a.i./A/yr. Potatoes typically are cultivated in acid soils (pH <6). In these acidic conditions vinclozolin could be more persistent than for crops grown in neutral or slightly acidic conditions because hydrolysis, a major route of dissipation, proceeds slowly when pH is below 7.

For succulent beans the maximum rate is two applications at 2 lb a.i./A for a total of 4 lb a.i./A/yr. On grapes the maximum is four applications at 2 lb a.i./A for a maximum of 8 lb a.i./A/yr. Aerial and chemigation application methods are allowed for potatoes and succulent beans. For grapes a directed spray is applied to fruit.

To support these terrestrial food uses, additional information for the following data requirements are needed: hydrolysis (161-1), photodegradation on soil (161-3), aerobic soil metabolism (162-1), leaching and adsorption/desorption (163-1), and terrestrial field dissipation (164-1); see 7.2 above for details. Droplet size spectrum (201-1) and Drift field evaluation (202-1) data may be needed by EFED/Ecological Effects Branch and/or HED to support the aerial, chemigation, and air blast application methods.

7.5 Registrant's Response to Previous EFGWB Review

An EFGWB review of 02/22/90 noted that field dissipation data for vinclozolin were not sufficient to support a new use on almonds. The registrant replied on 06/15/90 indicating that new field studies had been conducted and that these data were sufficient to support the new use. Except for the issues related to the status of the field dissipation data requirement (164-1) noted in section 7.2 (i) above, EFGWB concurs with the registrant's response to the EFGWB review.

8.0 RECOMMENDATIONS:

Although the overall environmental fate assessment for vinclozolin is not likely to be changed, additional information related to the following data requirements is needed to support terrestrial uses: hydrolysis (161-1), photodegradation on soil (161-3), aerobic soil metabolism (162-1), leaching and adsorption/desorption (163-1), and terrestrial field dissipation (164-1). The specific information needed to fulfill each data requirement is outlined in section 7.2.

In two cases, however, EFGWB believes that the requested data are particularly important. First, K_d values have been requested for metabolite B. These data are needed because metabolite B is formed early in the degradation process. Given its rapid formation, it is possible that metabolite B has biological activity and contributes to the pesticidal properties of vinclozolin. Soil column studies indicate that metabolite B is potentially mobile, but the information available from these studies is only qualitative. K_d

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values for metabolite B will enable a more quantitative estimate of the potential mobility of this key degradation product. Kd for metabolite B may be needed for model simulations which assess the potential of vinclozolin residues to contaminate surface waters.

Also, frozen storage stability data for individual analytes (parent vinclozolin plus metabolites B, D, and E) in soil are needed to increase confidence in the field dissipation studies. This information is important because much of EFGWB's assessment is based on four field dissipation studies. See section 7.2 (i) for details.

To support the forestry use, aerobic aquatic metabolism (162-4) and forest field dissipation (164-3) data are needed. These studies have not been submitted. Application to forests is likely to result in exposure to bodies of water and in dissipation patterns which may not be addressed by the terrestrial use data set. In addition, the information needed to fulfill the data requirements for terrestrial uses (see above) is needed to support the forestry use.

8.1 Ground Water

Because degradates of vinclozolin are mobile and can be persistent under certain environmental conditions, the chemical has the potential to impact ground water quality. For this reason, EFGWB recommends that all product labels carry the following advisory:

> "This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Because the reference dose and carcinogenicity of vinclozolin are under review, a final assessment of the human health effects from drinking water cannot be established at this time. After the peer review committee meeting (summer 1995), further recommendations related to ground water will be made. Refer to the attached Ground Water Assessment for details.

8.2 Surface Water

Vinclozolin can be transported to surface water at application via spray drift from aerial and ground applications. Also, vinclozolin and its degradation products could be available for runoff for several weeks to months post-application. Vinclozolin is not one of the 48 pesticides EEB believes pose the greatest aquatic and/or avian risks. Consequently, EFGWB does not believe that any monitoring of surface waters for vinclozolin is needed at this time to assess aquatic risk. EFGWB defers to HED on whether to recommend monitoring of surface drinking water supplies for vinclozolin and its major degradates.

EFGWB does not currently believe that the potential risks of vinclozolin to aquatic non-target organisms is sufficient to warrant a surface water advisory on the label. However, EFGWB defers to HED on whether a surface water advisory is necessary to protect surface drinking water supplies.

If a decision is made to generate a labeling surface water advisory for vinclozolin, EFGWB recommends the following wording in addition to any on spray drift or application buffers for surface waters:

"Vinclozolin can contaminate surface water through spray drift. Under some conditions, vinclozolin may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."

Refer to the attached Surface Water Assessment for details.

B.3 Status of Environmental Fate Data Requirements

Data Requirement	Status	MRID Number
Degradation		
161-1 Hydrolysis	Partially fulfilled	41471006
161-2 Photolysis in water	Fulfilled	42394706
161-3 Photolysis on soil	Not fulfilled	41471008
161-4 Photolysis in air[1]	Not required	
Metabolism		
162-1 Aerobic soil	Not fulfilled	88288, 136376, 136377, 43013001
162-2 Anaerobic soil	Fulfilled	41471009
162-3 Anaerobic aquatic[2]	Not fulfilled	43013002
162-4 Aerobic aquatic[3]	Not fulfilled	
Mobility		
163-1 Leaching, Adsorption/ Desorption	Not fulfilled	41471010, 41888904 136381, 41496904
163-2 Volatility-lab	Fulfilled	42513101
163-3 Volatility-field[1]	Not required	
Dissipation		
164-1 Terrestrial	Not fulfilled	41538301, 42687601 42717401, 43102601 42327301

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Status of Environmental Fate Data Requirements (continued)

Dissipation (continued)

164-2 Aquatic[4]	Not required	
164-3 Forest[3]	Not fulfilled	
164-5 Terrestrial, long-term	Not required	

Accumulation

165-4 Fish	Fulfilled	42847001, 136387

Spray Drift

201-1 Droplet size spectrum[5]	Reserved	
202-1 Drift field eval.[5]	Reserved	

Footnotes:

[1] The study is not needed at this time because laboratory data indicate that volatility from soil is not likely to be an important route of dissipation.

[2] Because the anaerobic soil metabolism study is acceptable and there are no aquatic uses of vinclozolin, anaerobic aquatic metabolism data are not needed at this time.

[3] These studies are needed to support the forestry use.

[4] According to SRRD there are no current aquatic uses, therefore these data are not needed at this time.

[5] If these data are needed by EFED/EEB and/or HED, the registrant may pursue fulfillment of these data requirements through the Spray Drift Task Force. The procedures outlined in PR Notice 90-3 should be followed.

9.0 BACKGROUND:

Vinclozolin is a fungicide used to control *Botrytis* spp. in fruits, vegetables, turf, and ornamentals. It also has forestry uses. Application methods include thermal fogging for foliar coverage on ornamentals, aerial, airblast, and ground boom applications.

10.0 DISCUSSION: See Conclusions, Recommendations, and DERs

11.0 ONE-LINER: Attached.

12.0 CBI APPENDIX: N/A

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

5/15/95

NOTE

SUBJECT: Ground-Water Assessment for RED Science Chapter on Vinclozolin

TO: Skee Jones
EFGWB/EFED

FROM: Estella Waldman
EFGWB/EFED EW

THRU: Blizabeth Behl, Section Head
Ground Water Technology Section
EFGWB/EFED
EB

AND: Henry M. Jacoby, Branch Chief
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division
Henry Jacoby 5/14/95

GROUND WATER ASSESSMENT
VINCLOZOLIN

The degradates of vinclozolin demonstrate the properties and characteristics associated with chemicals that have been detected in ground water. These characteristics include resistance to hydrolysis at certain pH's, relative stability in soil under aerobic and combined anaerobic/aerobic conditions, and high mobility in soils. Field dissipation data confirm that vinclozolin can be persistent, especially for one of the metabolites (D) which was also detected to a depth of 30 inches in soil.

The Agency does not have any reports of vinclozolin detections in ground water, although it is not an analyte in most ground-water studies and is not reported in the Pesticides in Ground Water Database.

A lifetime Health Advisory (HAL) or MCL for vinclozolin has not been established. The Reference Dose and Cancer Group classification for the chemical are based on "old" (1982) data that will be re-evaluated during the summer of 1995. At present, the reference dose is listed as 0.025 mg/kg-day (reference dose includes all degradates) and vinclozolin is classified as a Group B carcinogen. After the Health Effects Division peer review committee meeting, the reference dose and the Cancer Group may change significantly (Dave Anderson, HED, 5/4/95). Depending on the outcome of the peer review, the estimated HAL may also significantly change.

Based on our current knowledge about human and ecological endpoints at the present time, potential concentrations of vinclozolin in ground water are not likely to exceed risk-based Levels of Concern for ecological effects. However, vinclozolin is likely to exceed one of the risk-based levels of concern for ground water as follows:

- **Ground-Water Quality.** Because degradates of vinclozolin are mobile and can be persistent under certain environmental conditions, the chemical has the potential to impact ground-water quality.

<u>Recommendations</u>

1. Vinclozolin has the potential to contaminate ground water. For this reason, EFGWB recommends that all product labels carry the following advisory:

   > "This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

2. Because the reference dose and carcinogenicity of vinclozolin are under review, a final assessment of the human health effects from drinking water cannot be established at this time. After the peer review committee meeting (summer 1995), further recommendations related to ground water will be made.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 27, 1995

MEMORANDUM

TO: Paul Mastradone, Ph.D., Chief
Review Section 1, EFED/EFGWB

FROM: for Henry Nelson, Ph.D., Chief
Surface Water Section, EFED/EFGWB

SUBJECT: Vinclozolin - Surface Water Assessment

The following is the surface water assessment for vinclozolin for inclusion in the EFGWB RED chapter.

Surface Water Assessment for Vinclozolin

Vinclozolin will be transported to surface water at application via spray drift from aerial, air blast, and ground spray applications. Substantial quantities of vinclozolin could also be available for runoff for several weeks to months post-application. Although initial degradation rates in soil under aerobic conditions were reported to be fairly rapid (initial $t_{1/2}$ = 5-7 days), biphasic second half-lives were substantially longer ($t_{1/2}$ = 46-50 days) in an aerobic soil metabolism study. Average half-lives of 35-53 days were reported over the entire duration of four supplemented aerobic soil metabolism studies. The relatively low soil/water partitioning of vinclozolin (Freundlich adsorption binding constants < 5.2) indicates that most vinclozolin runoff will occur via dissolution in runoff water as opposed to adsorption to eroding soil.

Vinclozolin should undergo rapid hydrolysis in the water columns of alkaline to neutral waters (abiotic hydrolysis half-lives of 38 minutes and 31 hours at pHs 9 and 7, respectively). However, vinclozolin should be somewhat more persistent in acidic waters with long hydrological residence times and low microbiological activities. Its hydrolysis rate declines rapidly with decreasing pH (half-life of 42 days at pH 5), it is only moderately susceptible to direct aqueous photolysis (irradiated half-life of 15.9 days compared to a dark control half-life at pH 5 of 38.1 days), and it is not very volatile (Henry's Law constant = 3.8×10^{-7} atm*m^3/mol. Under the anaerobic conditions encountered in many sediments, vinclozolin may be moderately susceptible to degradation (anaerobic soil metabolism half-life of 15 days). Based upon the results of studies in soil under aerobic conditions, vinclozolin may be susceptible to initially rapid biodegradation in some waters with high microbiological activities. However, it is unclear whether subsequent biodegradation rates would be substantially slower like

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they typically are in soil. The relatively low soil/water partitioning of vinclozolin indicates that most of the vinclozolin in aquatic systems will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment. BCFs for vinclozolin in the bluegill sunfish (106-143X, 317-421X and 241-279X for edible, non-edible, and whole fish tissue, respectively) along with rapid and extensive depuration indicates that the bioaccumulation potential of vinclozolin is relatively low.

Major primary degradates of vinclozolin are N-(3,5-dichlorophenyl) carbamic acid (1-carboxyl-1-methyl)-2-propenyl ester (degradate B) and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (degradate E). A major secondary degradate formed from primary degradate E is 3,5-dichloro aniline (degradate D). The persistence of degradates B and E in soil under aerobic conditions appear to be somewhat comparable to that of vinclozolin, but the persistence of secondary degradate D is much greater. Consequently, substantial quantities of degradate D should be available for runoff longer than vinclozolin and its primary degradates B and E. Likewise, degradate D should be somewhat more persistent in surface waters. The mobility of degradates B, E, and D vary somewhat, but are generally either comparable to or greater than that of vinclozolin. Consequently, like vinclozolin, their runoff should occur primarily by dissolution in runoff water (as opposed to adsorption to eroding soil) and they should exist in aquatic systems primarily dissolved in the water column (as opposed to adsorbed to suspended and bottom sediments).

Vinclozolin is not one of the 48 pesticides EEB believes pose the greatest aquatic and/or avian risks. Consequently, EFGWB does not believe that any monitoring of surface waters for vinclozolin is needed at this time to assess aquatic risk.

Vinclozolin is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, no MCL has been established for it and water supply systems are not required to sample and analyze for it. In addition, no acute or chronic drinking water health advisory levels (HALs) have been established for it. However, HED includes vinclozolin on its list of "Apparent Exceeders (Chronic Effects and Cancer)" and as potentially acutely toxic as well based upon potential dietary exposure. In addition, the low soil/water partitioning of vinclozolin and its major degradates suggests that they will not be effectively removed by the primary treatment processes employed by most surface water supply systems. Consequently, EFGWB defers to HED on whether to recommend monitoring of surface drinking water supplies for vinclozolin and its major degradates.

EFGWB does not currently believe that the potential risks of vinclozolin to aquatic non-target organisms is sufficient to warrant a surface water advisory on the label. However, EFGWB defers to HED on whether a surface water advisory is necessary to

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protect surface drinking water supplies.

If a decision is made to generate a labeling surface water advisory for vinclozolin, EFGWB recommends the following wording in addition to any on spray drift or application buffers for surface waters:

Vinclozolin can contaminate surface water through spray drift. Under some conditions, vinclozolin may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 27, 1995

MEMORANDUM

TO: Paul Mastradone, Ph.D., Chief
Review Section 1, EFED/EFGWB

FROM: for Henry Nelson, Ph.D., Chief
Surface Water Section, EFED/EFGWB

Henry Jacoby

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they typically are in soil. The [illegible] partitioning of vinclozolin indicates that most of the vinclozolin in aquatic systems will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment. BCFs for vinclozolin in the bluegill sunfish (106-143X, 317-471X and 241-279X for edible, non-edible, and whole fish tissue, respectively) along with rapid and extensive depuration indicates that the bioaccumulation potential of vinclozolin is relatively low.

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protect surface drinking water supply(s)).

(4)

If a decision is made to generate a labeling surface water advisory for vinclozolin, EFGWB recommends the following wording in addition to any on spray drift or application buffers for surface waters:

Vinclozolin can contaminate surface water through spray drift. Under some conditions, vinclozolin may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water.